FUJIFILM
Fujifilm Medical Systems, USA

K081308

JUN - 4 2008

SECTION 5

SPECIAL 510(K) SUMMARY

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Fujifilm Medical Systems, USA

Special 510(k) Summary

Date: May 5, 2008

Contact Person:

Name:	Debbie Peacock
Title:	Regulatory Coordinator
Telephone:	(203) 602-3774
Facsimile:	(203) 363-3813

Identification of Device:

Proprietary/Trade Name:	FCR View
Classification:	Class II
Classification Name:	PACS
Product Code:	LLZ
Common Name:	PACS

I. INDICATIONS FOR USE

FCRView (CR-VW 674) is a Workstation intended to associate FCR images with patient and exam information, apply images processing to facilitate diagnosis, display the images, and output the resulting image and exam data for further display, distribution, or archiving. In addition, the FCR View can receive DICOM multi modality images for viewing. The FCR View must not be used for primary diagnosis of mammography images.

II. DEVICE DESCRIPTION

The FCRView is an image viewer workstation that offers a fully integrated solution for managing the CR modality, as well as built-in viewing, archiving and distribution capabilities. It can import and display ultrasonic images and general-purpose images from digital cameras, and other general purpose images (such as jpeg images) on screen and/or print via a typical paper printer. Images captured on the FCR reader unit are displayed on the FCRView along with typical tools to aid in reading the images. The FCRView also incorporates a built-in archiving and CDR/DVDR image output system.

A summary description of the key features of the system follows:

- FCRView (CR VW 674) is a modality and Image Viewing workstation intended to associate FCR images (except mammography images) with patient and exam information, and apply image processing to facilitate diagnosis.
- Currently interfaces with Fuji CR and also accepts images from other modalities such as Ultrasound as well as general purpose (jpg) images.
- FCRView incorporates a built-in archiving and CDR/DVDR image output system

III. SUMMARY OF STUDIES

The FCRView has been evaluated for electrical, mechanical and radiation safety and conforms with applicable medical device safety standards.

IV. SUBSTANTIAL EQUIVALENCE

The Fujifilm FCR View covered by this submission is a modification to and is substantially equivalent the Fujifilm CR Console (K041990) cleared by CDRH on 08/06/04 and the FCR AXON (Class I Exempt) image management and communication device. The combination of both Fujifilm devices utilizes similar technology and materials, comparable safety and effectiveness features, and are similar in design and construction to our proposed modified device. .

The Indications for Use for the proposed device is the same as the combined Indications for Use of the Fuji CR Console and the FCR AXON (Exempt). In addition, the labeling for all three devices are the same.

V. CONCLUSION

The FCRView is a modification to and substantially equivalent to our currently cleared CR Console (IIP) along with the image archive and retrieval functionality found in our Class I AXON product, and conforms to applicable medical device safety standards. The modifications do not change the indications for use, introduce new technology or significantly affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Ms. Debbie Peacock
Regulatory Coordinator
FUJIFILM Medical Systems USA
419 West Avenue
STAMPFORD CT 06902

Re: K081308
Trade/Device Name: FCRView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 5, 2008
Received: May 9, 2008

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

FUJIFILM
Fujifilm Medical Systems, USA

Indications for Use

510(k) Number (if known): _____

Device Name: FCRView

Indications for Use:

FCRView (CR-VW 674) is a Workstation intended to associate FCR images with patient and exam information, apply images processing to facilitate diagnosis, display the images, and output the resulting image and exam data for further display, distribution, or archiving. In addition, the FCR View can receive DICOM multi modality images for viewing. The FCR View must not be used for primary diagnosis of mammography images.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081308